

REMARKS/ARGUMENTS

Claims 1, 2, 5-17, and 19-21 have been examined. Applicants note with appreciation that dependent claims 19 and 20 define allowable subject matter. Claims 1, 12, 16, 17, 19, and 21 have been amended. Claims 8-11 and 18 have been canceled. New claims 43-58 have been added. Support for the new claims can be found throughout the originally filed disclosure and claims. In particular, new independent claim 43 is respectively allowable claim 19 rewritten in independent form including substantially all base limitations. As such, new independent claim 43 (and dependent claims 44-58) should be in condition for allowance. Claims 3 and 4 stand withdrawn. Applicants believe independent claim 1 remains generic. Re-examination and reconsideration of pending claims 1-7, 12-17, and 19-21 is respectfully requested.

As an initial matter, Applicants request that the Examiner send confirmation of the consideration of the references cited in the Information Disclosure Statement (IDS) filed by Applicants on September 5, 2001. As requested by the Examiner, the above-noted IDS with the return filing card was faxed to the Examiner on June 9, 2004.

Rejections under 35 U.S.C. §102

Claims 1, 2, 5, 8-17, and 21 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent No. 6,200,257 issued to Winkler. This rejection is respectfully overcome in part and traversed in part as follows.

To more clearly claim the present invention as well as expedite prosecution of the present case, independent claim 1 has been amended to include the limitation of canceled claim 11. Claim 1 now recites a catheter comprising a catheter body, an ionizing radiation source, a source of at least one radiosensitizer, a balloon coupled to the catheter body, and *a matrix formed over at least a portion of the balloon* for releasing the radiosensitizer. Further, it is recited that the *radiosensitizer source is in or beneath the matrix and the balloon is free of the radiosensitizer source*. Such positive structural limitations of a matrix formed over at least a portion of the balloon, wherein the radiosensitizer source is in or beneath the matrix and the

balloon is free of the radiosensitizer source have not been reasonably shown or suggested by the cited art.

As the Examiner certainly knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. §102. M.P.E.P. §2131; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974) ("All words in a claim must be considered in judging the patentability of that claim against the prior art."). The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the claim." *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

The Winkler reference describes a catheter (10) having a permeable hydrogel membrane balloon (20) that is inflatable with therapeutic agents and an insertion tube (30) having radioactive pellets (32) to irradiate the agent within the membrane balloon to create a radiosensitizing effect on the surrounding tissue in contact with the membrane balloon, as illustrated in Figs. 1B and 3. However, this reference fails to teach or suggest a matrix formed over at least a portion of the balloon, much less a radiosensitizer source in or beneath the matrix and a balloon free of the radiosensitizer source. Winkler is limited to agent delivery via the membrane balloon, which clearly contains the agent. The present invention now requires a different and distinct structural component for releasing the radiosensitizer, namely a separate matrix (21) formed over a balloon (18'), wherein the radiosensitizer source (19) is in or beneath the matrix and the balloon is free of the radiosensitizer source (19), as shown in Figs. 3B and 3C of the present application.

"Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. . . . There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention." *Scripps Clinic & Research Found. v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991). Applicants request that if the present rejection is maintained, the Examiner show or explain where the Winkler patent reference teaches or suggest the distinct structural limitations of a matrix formed over at least a portion of the balloon, wherein the radiosensitizer source is in or beneath the matrix and the balloon is free of the radiosensitizer

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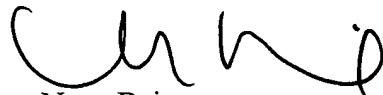
source. Absent such a showing, Applicants respectfully request withdrawal of this rejection and allowance of independent claim 1 (and dependent claims 2-7, 12-17, and 19-21).

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Nena Bains
Reg. No. 47,400

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 415-576-0200
Fax: 415-576-0300
Attachments
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